California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Legislation and Regulation Committee

Andrea Zinder, Board Member and Chair
Tim Daze, Board Member
Hank Hough, Board Member
Ken Schell, PharmD, Board Vice President

There has been no meeting of the Legislation and Regulation Committee this quarter. Instead, the committee will meet at the end of today's board meeting to discuss future legislation and regulation proposals. A portion of committee agenda has been set to enable those with regulation or legislative proposals to present these items to the committee.

1. Overview of the Regulation Adoption Process

Board Manager Anne Sodergren will provide a presentation on how an idea becomes a regulation. The regulation process is very specific, and there are a number of steps and timelines that an agency must follow when adopting a regulation.

REGULATION REPORT

2. Board Action on Regulations

At this meeting the board has the opportunity to act on two regulations. Each of these regulations has undergone the required 45 days of public comment and is ready for board action at this meeting. Both regulations were released without a public hearing scheduled, and no hearing was requested.

A motion is required by the board to act on each regulation.

a. Proposed Repeal of Title 16 California Code of Regulations Section 1717.2 – Notice of Electronic Prescription Files

Rulemaking documents for this regulation are in **Attachment 1**.

The repeal of this outdated regulation would remove a barrier that prevents pharmacists, in certain situations, from having full knowledge of all the prescription drugs that a patient is taking. Removing this barrier will result in better patient care without compromising patient medical record privacy. The regulation was promulgated in the 1980s when pharmacies first started using computers and before HIPAA and California laws were enacted to protect patient privacy.

This proposal was publicly noticed in August 2006. No comments were received during the comment period.

b. Proposed adoption of Title 16 California Code of Regulations section 1784 - Self-Assessment of a Wholesaler by the Designated Representative-In-Charge

Rulemaking documents for this regulation are in **Attachment 2**.

This regulation would establish requirements that the designated representative-in-charge (DRC) of a licensed wholesaler must complete a self-assessment form to ensure compliance with pharmacy law. This self-assessment form will aid wholesalers in complying with legal requirements of wholesaler operations, and therefore increase public safety as a result of this compliance. Additionally, the proposal would make the pharmacy inspection process more meaningful and provide relevant information to wholesalers and their DRCs. This regulation is modeled after a similar requirement for pharmacies -- pharmacies must perform a self-assessment every two years or upon a change in the pharmacist-in-charge.

This proposal was publicly noticed in August 2006. No comments were received during the comment period. However because of changes in federal and state law, revisions must be made to update the draft necessitating an additional 15-day comment period.

The board may adopt this proposal at this board meeting and delegate to the interim executive officer the authority to submit the rulemaking file if no negative comments are received during the required 15-day notice period.

3. Approved Regulations – Section 1727.1 Exemption for Intern Address from Posting Online

The Office of Administrative Law approved the board's rulemaking to allow the addresses of records of intern pharmacists to be removed by posting on the board's Web site. The regulation took effect on October 1, and the board's technical staff is working to remove this component from the board's Web site.

The addresses of record of intern pharmacists will still be available upon written request to the board.

The text of this regulation is provided in **Attachment 3**.

4. Pending Regulations

a. Board Approved – Pending Administration Approval

1. Sections 1713 and 1717(e) – Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions

On April 26, 2006, the board voted to amend section 1717(e) and adopt section 1713. These actions would allow pharmacy patients the ability to use a vending-like machine located near a pharmacy counter to obtain their refill medication. The regulation would also allow the use of prescription drop-off boxes outside a pharmacy as a means to leave prescriptions for pharmacies to later pick up and fill.

Staff completed the necessary 15-day notice in May 2006 to incorporate changes approved by the board during the April Board Meeting. No new comments were received relevant to the specific changes made by the board, so the rulemaking file was submitted to the department for administrative review and approval in early August 2006.

The Department of Consumer Affairs is still reviewing this file. After completion of this review, the rulemaking file will then be provided to the Office of Administrative Law, which has 30 working days to review it. This regulation will be effective early next year.

Attachment 4 contains the regulation language.

2. Sections 1793.7 and 1793.8 – Pharmacy Technicians Checking Pharmacy Technicians in an Acute Care Pharmacy

On April 26, 2006 the board approved an amendment to section1793.7 and to adopt CCR 1793.8 to define the conditions under which a pharmacy technician may check the work of another pharmacy technician.

Board staff added materials to the rulemaking file (to formally admit underlying studies, written legal opinions and other relevant background information) which required a 15-day notice. The rulemaking file was submitted to the department for administrative review and approval in August 2006.

The Department of Consumer Affairs is still reviewing this file. After completion of this review, the rulemaking file will then be provided to the Office of Administrative Law, which has 30 working days to review it. This regulation will be effective early next year.

Attachment 5 contains the regulation language.

b. Board Approved – Awaiting Notice

1. **Amend section 1706.2 – Abandonment of Application Files for Veterinary Food-Animal Drug Retailer, Hypodermic Needle and Syringe Distributor and Designated Representative**

   This section contains provisions establishing when an applicant has abandoned an application. However, applications for Veterinary Food-Animal Drug Retailers, Hypodermic Needle and Syringe Distributors and Designated Representatives are not included. This proposal would add these licensing programs to the regulation to make the board's application processes consistent.

2. **Amend CCR 1760 - Disciplinary Guidelines**

   This rulemaking would allow the board to use a revised 2007 edition of the Disciplinary Guidelines when deciding appropriate discipline action to take for violations of Pharmacy Law. Final revisions are being completed and this proposal will be noticed so that action can be taken at the January 2007 Board Meeting.

3. **Amend CCR 1775.4 – Reschedule of an Office Conference to Contest a Citation**

   In 2003, the board revised its system for issuing citations to make the procedures more consistent with other agencies within the Department of Consumer Affairs. During the revision process, a provision from CCR 1775(a) that permits an individual or entity to reschedule an office conference only once was left out of the regulation. This proposal will restore this provision.

4. **Repeal CCR 1786 – Exemptions for a Supplier**

   This section is outdated and needs to be repealed. This provision requires a supplier to immediately return a certificate of exemption to the board if an exemptee leaves the employment of a wholesaler. This regulation is based on prior Pharmacy Law which linked an exemptee license (designated representative) to a specific licensed wholesaler location.

5. **Board omnibus regulation provisions involving technical clean up for 2006**

   16 CCR § 1709.1 - Designation of Pharmacist in Charge
   16 CCR § 1780 - Minimum Standards for Wholesalers
   16 CCR § 1780.1 - Minimum Standards for Veterinary Food-Animal Drug Retailers

16 CCR § 1781 - Exemption Certificate

c. Board Approved – Proposed Language to be Developed

At the April Meeting, the board agreed to move forward with a proposed regulation on the process and criteria to approve accreditation agencies for pharmacies that compound sterile injectable sterile drug products. Language will be developed for the next Legislation and Regulation Committee.

d. Board Approved – Awaiting Conformance with California Building Standards Rulemaking Process

Addition to the California Building Code – 24 CCR 490A.3 and 505.12.2 Related to Compounding Parenteral Solutions; Technical Changes to the Building Code Relating to Pharmacies

On April 26, 2006, the board voted to amend the language in the California Building Code, Title 24, California Code of Regulations, section 490A.3 and 505.12 with respect to the building standards for pharmacies that compound parenteral solutions. This summer, the Building Standards Commission advised the board that there is a new process to submit items into the California Building Code. The board will pursue this new format in the future to secure the adoption of these standards into the building code.

Attachment 1

Repeal California Code of Regulations 1717.2 – Notice of Electronic Prescription Files

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on October 9, 2006.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 5 p.m. on September 25, 2006.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposal substantially as described below or may modify such proposal if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by section 4005 of the Business and Professions, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

The board proposes the repeal of Section 1717.2 in Title 16 of the California Code of Regulations. This section requires pharmacies that use and share electronic files with other pharmacies, to notify their customers that the customer can choose not to have their files shared with other pharmacies. This regulation is obsolete given the enactment of state and federal law that provides protection and confidentiality of patient medical records.

In addition repealing this regulation removes a barrier that prevents pharmacists, in certain situations, from having full knowledge of all the prescription drugs that a patient is taking. Removing this barrier will result in better patient care while protecting patient medical record privacy. Also, this regulation is in conflict with reporting requirements detailed in the Health and Safety Code.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None.

Business Impact: The proposed regulatory action would repeal a regulation that requires pharmacies that share electronic files with other pharmacies, to notify their customers that the customer can choose not to have their files shared with other pharmacies. Because the regulation is being repealed, the Board of Pharmacy has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business: The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small business. The Board of Pharmacy has made this determination because the proposed regulatory action would repeal a regulation that requires pharmacies that share electronic files with other pharmacies, to notify their customers that the customer can choose not to have their files shared with other pharmacies.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 1625 N Market Blvd. N219, Sacramento, California 95834, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulation is based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Virginia Herold
Address:	1625 N Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7911
Fax No.:	(916) 574-8618
E-Mail Address:	virginia_herold@dca.ca.gov

The backup contact person is:

Name:	Karen Cates
Address:	1625 N Market Blvd N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7914
Fax No.:	(916) 574-8618
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Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Notice of Electronic Prescription Files

Sections Affected: Repeal 1717.2

Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes repealing section 1717.2 of Division 17 of Title 16 of the California Code of Regulations. The purpose for repealing the regulation is to remove a now-outdated barrier that prevents pharmacists, in certain situations, from having full knowledge of all the prescription drugs that a patient is taking. Removing this barrier will result in better patient care while protecting patient medical record privacy because of other federal and state laws. Additionally, there is now federal and state legislation in place to better protect a consumer's medical information without compromising a consumer's safety.

Factual Basis/Rationale

Section 1717.2, adopted in 1986, requires pharmacies that use and share electronic files with other pharmacies, to notify their customers that the customer can choose not to have their files shared with other pharmacies.

Both state and federal laws protect the confidentiality of patients' electronic medication records. Section 1717.2 was adopted before state and federal laws were enacted to address this issue. This section is now obsolete and conflicts with Health and Safety Code section 11165.

In 1996, the federal government enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to improve the efficiency and effectiveness of the health care system. HIPAA included provisions designed to encourage electronic transactions while protecting the security and confidentiality of health information. In December 2000, the Department of Health and Human Services (HHS) published a final regulation in the form of privacy rules in response to the HIPAA mandate. This Privacy Rule set national standards for the protection of health information, as applied to three types of covered entities: health plans, health care clearinghouses, and health care providers who conduct certain health care transactions electronically. The rule established for the first time a foundation of federal protections for the privacy of protected health information and the imposition of substantial civil or criminal penalties against those entities that failed to comply with the implementation date. The HIPAA Privacy Rule gives individuals a

fundamental right to be informed of the privacy practices of their health plan and of most of their health care providers, as well as to be informed of their privacy rights with respect to their personal health information.

In 2000 California enacted the Confidentiality of Medical Information Act, Civil Code 56.10. This act states that no provider of health care, health care service plan or contractor can disclose medication information regarding a patient or the provider without first obtaining an authorization. While this act does provide for some exceptions, the act is explicit when these exceptions can occur and provides several safeguards for consumers to ensure the protection of their medical records.

In addition to these subsequent pieces of legislation, existing Section 1717.2 is in conflict with the Medi-Care Part D requirements as detailed in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). Specifically, the Medi-Care Part D program requires mandatory coordination of a patient's pharmacy records to ensure coverage under the plan. Because of program nuances, a patient's coverage may not be applicable during a period referred to as the "doughnut hole." If patients' are allowed to elect out of the electronic system, it renders the benefits of the Medi-Care Part D program totally ineffective because a patient's pharmacy services cannot be confirmed. In this scenario, it is the consumer who loses out on additional benefits and coverage they may be entitled to should they have chosen not to elect out of a computer system.

Section 1717.2 also impedes a pharmacist's ability to complete a thorough drug utilization review of a patient's drug history, because certain medication information may not be available to the pharmacist to review. This could result in consumer harm and or death because of drug allergies and or serious drug interactions. Specifically, prior to dispensing a new prescription, a pharmacist reviews a patient's drug history, drug allergies and current medications. This information is only available if it is contained within the pharmacy's computer system and can be shared. If a patient opts out of the computer system, it negates the drug utilization review which can be a life saving measure. Repealing Section 1717.2 can reduce adverse drug reactions and even save lives. Moreover, existing board regulation Section 1775.1(b) allows the board to cite and fine a pharmacy or pharmacist as specified in Section 56.36 of the Civil Code for failure to maintain the confidentiality of a patient's medications and health care. Specifically, Section 56.36 states that any licensed health care professional, who knowingly and willfully obtains, discloses or used medication information in violation of this act for financial gain shall be subject to an administrative of $5,000 per violation, up to $250,000 for subsequent violations.

Health and Safety Code section 11165 provides for the electronic monitoring of prescribing and dispensing of Schedule II and III controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program. (Currently pending California legislation could extend this to also include Schedule IV drugs.) This law states that for each prescription for a Schedule II or III controlled substance, the dispensing pharmacy must provide information to the Department of Justice (DOJ),

including the name, address, gender and date of birth of the patient, the National Drug Code (NDC) number of the controlled substance dispensed as well as the quantity dispensed, issue date of the prescription and dispensing date of the prescriptions. There are no exceptions to this reporting requirement. As such, the pharmacy must maintain this information and provide it to the DOJ, even if the patient directs that the information not be shared.

With today's substantial laws in place to protect consumers' medical record information, it seems appropriate for the board to review the usefulness of Section 1717.2.

For all of the reasons sited above the board is pursing the repeal of Section 1717.2 of the California Code of Regulations.

Underlying Data

California Civil Code 56.10
Health and Safety Code section 11165
45 Code of Federal Regulations Parts 160 and 164
The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)

Business Impact

This regulation will not have a significant adverse economic impact on businesses.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to repealing the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the repeal of the regulation.

Board of Pharmacy
Specific Language for Repeal of Section 1717.2

Repeal Section 1717.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~**§1717.2. Notice of Electronic Prescription Files.**~~

~~(a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:~~

~~NOTICE TO CONSUMERS:~~

~~This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies:~~

~~By offering this service, your prescriptions may also be refilled at the above locations. If for any reason you do not want your prescriptions to be maintained in this way, please notify the pharmacist-in-charge.~~

~~(b) Whenever a consumer objects to his or her prescription records being made accessible to other pharmacies through use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy, except as provided in Section 1764. The pharmacist to whom the consumer communicated the objection shall ask the consumer to sign a form which reads substantially as follows:~~

~~I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file.~~

~~(date)~~ ~~(signature of patient)~~

~~(acknowledgment of pharmacist)~~

~~The pharmacist shall date and co-sign the form, and shall deliver a copy thereof to the patient. The original shall be maintained by the pharmacy for three years from the date of the last filling or refilling of any prescription in the name of the consumer.~~

~~Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.~~

Attachment 2

Adopt Section 1784
Self Assessment of a Wholesaler
by the Designated Representative-
in-Charge

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on October 10, 2006.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 5 p.m. on September 24, 2006.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by section 4005 of the Business and Professions, and to implement, interpret or make specific sections 4022.5, 4201, and 4160 of the Business and Professions Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

The objective of this proposal is to provide designated representatives in charge (DRC) and the wholesaler premises with information regarding pharmacy law and the board's expectations for the practice of pharmacy within legal requirements. These are the elements reviewed by the board during unannounced inspections. A completed self-assessment form would serve as a reference for the DRC to use when managing wholesaler operations. Use of the self-assessment form in wholesalers could potentially reduce the need for DRC's to call the board with questions regarding pharmacy law.

The board is proposing to adopt section 1784 to require that the DRC of each wholesaler complete a self-assessment form according to specific criteria.

Additionally, section 1784 would detail the components of the self-assessment form for evaluating compliance with state and federal pharmacy laws regarding the condition of a wholesaler facility, DRC and owner responsibilities, drug stock, sale or transfer of drugs, delivery of drugs, policies and procedures and record keeping requirements. Specific sections referenced in the self assessment document include citations of the Business and

Professions Code (B & P), California Code of Regulations (CCR), Health and Safety Code (H & S) and Code of Federal Regulations (CFR).

The proposed regulation also specifies under what circumstances this self-assessment must be completed and the retention schedule for the form.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None.

Business Impact: The board determined that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

This action would provide the DRC with the specific compliance information that the board seeks when conducting a wholesaler inspection. The requirements for conducting a wholesaler outlined in the self-assessment are not new requirements. Wholesalers are currently required to comply with these laws.

The board intends that the DRC would actually determine the extent to which the wholesalers is or is not in compliance with Pharmacy Law, make necessary adjustments to bring the wholesaler into compliance and thereby improve the wholesaler's performance in meeting state and federal requirements. This would benefit public safety. Moreover, the assessment form provides wholesalers and the DRC with the knowledge they need to comply with state and federal requirements for licensed wholesalers.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business: The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

The proposal would necessitate a self-assessment by the DRC of the wholesaler premises every odd-numbered year or in the event of a change of location of the

licensed premises or change in the DRC. This self-assessment form would be a tool to aid the DRC and the wholesaler in general in this regard.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small business.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative which it considered either would be more effective than or as effective as and less burdensome on affected private persons than the proposal described.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd. N219, Sacramento, California 95834, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulation is based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Virginia Herold
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7911
Fax No.:	(916) 574-8618
E-Mail Address:	virginia_herold@dca.ca.gov

The backup contact person is:

Name:	Christine Sanchez
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Telephone No.:	(916) 574-7932
Fax No.:	(916) 574-8618
E-Mail Address:	Christine_sanchez@dca.ca.gov

Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Wholesaler Self-Assessment Form

Sections Affected: Add 1784

Specific Purpose of the Proposed Changes:

This section establishes requirements for the designated representative in charge (DRC) of a licensed wholesaler to complete a self-assessment form to ensure compliance with pharmacy law. This self-assessment form is to assist wholesalers in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the proposal would make the pharmacy inspection process more meaningful and provide relevant information to wholesalers and their DRC.

Factual Basis

The board is charge with protecting the public health, safety and welfare. Board of Pharmacy inspectors and staff accomplish this task in part by conducting inspections of wholesalers.

The DRC is responsible to assuring the premises compliance with state and federal requirements. Completing a self-assessment form would allow the DRC to increase the wholesaler's compliance with legal requirements without awaiting board inspection. The benefit to the public when a wholesaler is in compliance with the law is significant.

An inspector conducting an inspection is frequently asked questions regarding aspects of the inspections as well as clarifications and requirements of pharmacy law. This self-assessment form would provide an easy reference guide to the DRC when an inspector is not available.

The self-assessment form would confirm a DRC's understanding of the following pharmacy laws relevant to the operation of a licensed wholesaler including, facility standards, drug stock, the sale or transfer of drugs by the business, the proper controls for controlled substances and record keeping requirements. Specific sections referenced in the self assessment document include citations of the Business and Professions Code (B & P), California Code of Regulations (CCR), Health and Safety Code (H & S) and Code of Federal Regulations (CFR). Below is a brief description of the relevant sections of state and federal law referenced.

B & P 4160 details when a wholesaler license is required.

CCR 1780 defines the minimum standards for wholesalers

CCR 1781 defines the minimum standards for veterinary food-animal drug retailers.

B & P 4040.5 defines a "reverse distributor."

B & P 4181 discusses the licensing requirements, policies and procedures and who may dispense.

B & P 4331 details unlicensed activity and determines is to be misdemeanor.

B & P 4101 details the notification requirements for a designated representative in charge who terminates his or her employment at a licensed wholesaler.

B & P 4100 details the notification requirements for a designated representative who changes his or her name or address.

CCR 1704 details the reporting requires for licensees to notify the board of any change in address.

B & P 4163 prohibits the sale of drugs to unauthorized persons and the duty of the wholesaler to determine appropriate licensure prior to the sale of drugs.

B & P 4169 details the prohibitions for a wholesaler to sell to unlicensed entities.

B & P 4081 details the requirements for record keeping.

B & P 4332 makes it a misdemeanor for anyone who fails to maintain records as defined in pharmacy law.

B & P 4059.5(a) details who may order dangerous drugs and devices.

B & P 4167 prohibits the acquisition of drug product by a wholesaler that it cannot properly maintain and secure.

B & P 4342 authorizes the board to take action to prevent the sale of drugs under defined conditions.

CCR 1718 discusses the mandatory inclusion of the manufacturer's date on prescription drugs.

CFR 1307.21 details the procedure for disposing of controlled substances.

B & P 4163 details unauthorized furnishing by a manufacturer or wholesaler

B & P 4126.5 discusses furnishing dangerous drugs by a pharmacy.

H & S 111250 defines a drug or device that is adulterated.

H & S 111335 defines a drug or device that is misbranded.

B & P 4059.5 details the conditions under which dangerous drugs and devices may be ordered by a licensed entity.

B & P 4380 describes the prohibitions of the resale of preferentially priced drugs.

B & P 4341 discusses the advertisement of prescription drugs and devices.

B & P 651 details the professional advertising requirements.

CCR 1766 prohibits false or misleading advertising as described in Section 17500 of the B & P.

B & P 650 discusses the prohibition of rebates or discounts for referrals.

B & P 4066 details the procedures for a wholesaler to provide dangerous drugs to the master or first officer of an ocean vessel.

CFR 1301.25 discusses the registration regarding ocean vessels, aircraft and other entities.

B & P 4166 discusses the shipping of dangerous drugs and devices by a wholesaler or manufacturer.

CFR 1301.71 discusses general security requirements to ensure effective controls and procedures to guard against theft and diversion of controlled substances.

CFR 1301.72 (a) details the physical security controls for non-practitioners; narcotics treatment programs and compounders for narcotic treatment programs.

CFR 1304.11 details the inventory requirements.

CFR 1305.07 discusses the applicability of "power of attorney."

CFR 1301.90 discusses the employee screen procedures.

CFR 1301.92 discusses the employer's duties to address illicit activities by employees.

H & S 11153.5 prohibits the furnishing of controlled substances for anything other than a legitimate medical purpose.

CFR 1301.74 details other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

CFR 1305.03 discusses the order form required for each distribution of a Schedule I or II controlled substances as well as the exceptions.

CFR 1305.06 details the procedures for executing order forms.

CFR 1305.09 details the procedures for filling order forms.

CFR 1305.11 described the proper handling of an order form that is unaccepted or defective.

CFR 1305.12 details the procedure for executing DEA Forms 222.

CFR 1305.13 details the procedure for filing DEA forms 222.

H & S 11252 details the preservation of federally required forms.

H & S 11253 details the duration of retention of records.

CFR 1304.03 describes the requirements for persons required to keep records and file reports.

CFR 1304.04 details the maintenance and records of inventories.

CFR 1301.75 describes the physical security controls for practitioners.

CFR 1305.16 defines the procedures to address a lost or stolen DEA Form 222.

B & P 4054 allows a wholesaler to provide certain dialysis drugs and devices.

B & P 4059 prohibits the furnishing of dangerous drugs and devices without a prescription and details exceptions to this prohibition.

CCR 1787 discusses the authorization to distribute dialysis drugs and devices.

CCR 1790 details the information that must be maintained for shipment or expanded invoices and the duration of time the records must be kept for home dialysis drugs and devices.

CCR 1791 details the labeling requirements for home dialysis drugs and devices

B & P 4105 details the storage and retention of records for the acquisition and disposition of drugs.

CCR 1707 allows for the off-site storage of pharmacy records under certain conditions.

B & P 4162 details the surety bond requirement for wholesalers.

B & P 4083 discusses "orders of corrections."

B & P 4315 discusses "letters of admonishment."

B & P 4305.5 specifies the reporting requirements for the wholesaler when a change in designated representatives in charge occurs and that failure to notify appropriate can result in disciplinary action.

CCR 1715.6 details the reporting requirements for drug loss.

CFR 1301.91 details an employee responsibility to report drug diversion.

B & P 4201 details application requirements and notification requirements for a change of ownership.

B & P 4164 details reports required for controlled substances.

CCR 1705 details the reporting requirements for notification of bankruptcy, receivership or liquidation of licensed premises.

CCR 1708.2 details the reporting requirements for any licensee that is discontinuing business.

CFR 1301.52 details the termination of a registration issued and the conditions under which a transfer may occur upon a discontinuance of business.

CFR 1305.14 describes the requirement to return unused order forms.

B & P 4107 details the limitation on the number of licenses per site.

The board desires to provide all parties who must complete the self-assessment with a document that is straightforward and accurately represents the information they need to comply with California and federal requires for the practice of pharmacy.

Underlying Data

Business and Profession Code
California Code of Regulations
California Health and Safety Codes
Code of Federal Regulations

Business Impact

This regulation will not have a significant adverse economic impact on businesses.

This action would provide a DRC with the specific compliance information that the board seeks when conducting a wholesaler inspection. The requirements for conducting a wholesaler outlined in the self-assessment are not new requirements and wholesalers are already required to comply with them.

Using this form would benefit public safety.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

Board of Pharmacy
Specific Language to Add Section 1784

Add Section 1784 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new wholesaler permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler to a new address.

(c) The components of this assessment shall be on Form 17M-26 (rev. 8/14/2006) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.
(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4160 Business and Professions Code.

Attachment 3

Section 1727.1
Exemption for Intern Addresses of Record from Posting Online

Board of Pharmacy
Specific Language

Adopt Section 1727.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1727.1 Intern Pharmacist Address.

The Board shall not make an intern pharmacist's address publicly available on "Internet," as defined by Business and Professions Code section 17538.

Note: Authority cited: Section 4005 and 4100, Business and Professions Code. Reference: Section 4005 and 4100 Business and Professions Code.

Attachment 4

Section 1717(e) and 1713
Prescription Drop Boxes and
Automated Self-Use Delivery
Devices for Refill Prescriptions

Board of Pharmacy
Specific Language

15- DAY NOTICE

April 26, 2006

Adopt Section 1713 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1713. Receipt and Delivery of Prescriptions and Prescription Medications.

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d) A pharmacy may use an automated delivery device to deliver previously dispensed ~~refilled~~ prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.
(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication ~~mediation~~ to that patient.
(3) The device has a means to identify each patient and only release that patient's prescription medications.
(4) The pharmacy does not use the device to deliver previously dispensed ~~refill~~ prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).
(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.~~The pharmacy provides a means for each patient to obtain an immediate telephone or in-person consultation with a pharmacist if requested by the patient.~~
(6) The device is located adjacent to the secure pharmacy area~~licensed pharmacy counter~~.
(7) The device is secure from access and removal by unauthorized individuals.
(8) The pharmacy is responsible for the prescription medications stored in the device.
(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6)Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

Note: Authority cited: Sections 4005, 4075, and 4114 Business and Professions Code. Reference: Sections 4005, 4052, 4116 and 4117 Business and Professions Code.

Amend Section 1717 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1717. ~~Pharmaceutical~~ Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.

Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.

(e) ~~No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.~~

~~However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~

~~(f)~~ A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.

Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;

(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;

(3) Original date and last dispensing date;

(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

~~(g)~~ (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

Attachment 5

Section 1793.7 and 1793.8
Pharmacy Technician Checking
Pharmacy Technician in an Acute
Care Hospital Pharmacy

Board of Pharmacy
Specific Language

Amend Section 1793.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.7 Requirements for Pharmacies Employing Pharmacy Technicians.

(a) Except as otherwise provided in section 1793.8, any ~~Any~~ function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.
(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.
(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.
(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.
(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.
(f) For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

Note: Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Adopt Section 1793.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.8 Technicians in Hospitals with Clinical Pharmacy Programs.

(a) A general acute care hospital, as defined in Health and Safety Code 1250 (a), that has an ongoing clinical pharmacy program may allow pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist.
Only inpatient hospital pharmacies as defined in 4029(a) that maintain a clinical pharmacy services program as described in 4052 may have a technician checking technician program as described. The pharmacy shall have on file a description of the clinical pharmacy program prior to initiating a technician checking technician program.

(1) This section shall only apply to acute care inpatient hospital pharmacy settings.

(2) Hospital pharmacies that have a technician checking technician program shall deploy pharmacists to the inpatient care setting to provide clinical services.

(b) Compounded or repackaged products must have been previously checked by a pharmacist and then may be used by the technician to fill unit dose distribution systems, and floor and ward stock.

(c) To ensure quality patient care and reduce medication errors, programs that use pharmacy technicians to check the work of other pharmacy technicians pursuant to this section must include the following components:

(1) The overall operation of the program shall be the responsibility of the pharmacist-in-charge.

(2) The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures.

(3) The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility.

(4) To ensure quality there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

Note: Authority cited: Sections 4005, 4007, 4038, 4115, and 4202, Business and Professions Code.
Reference cited: Sections 4007, 4038, 4115 and 4202, Business and Professions Code.